APR 0 9 2014

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510(K) SUMMARY

V-total™

510(k) Number K133837

Applicant's Name: Viora Ltd.
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Contact Person: Yoram Levy, Qsite
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Binyamina, Israel 30500
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Trade Name: *V-total™*

Summary Preparation Date: December 12, 2013

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEX, PBX
Regulation No: 21 CFR 878.4400, 878.4810
Class: II
Panel: General and Plastic Surgery

Device Description:

The Viora V-total™ system is a multi application, multi-technology platform with four available treatment handpieces (applicators):

- ST Bi-polar radiofrequency (RF) handpiece
- Intense pulsed light (IPL) handpiece
- Long pulse neodymium-doped yttrium aluminum (Nd:YAG) laser handpiece

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Intended Use Statement:

The Viora ***V-total***™ is intended for dermatological procedures.

The **ST handpiece** is indicated for the treatment of relief of minor muscle aches and pain, relief of muscle spasm and temporary improvement of local blood circulation.

The IPL handpiece with wavelengths 415-1200nm (with 5 different filters) is indicated for the treatment of:

- Moderate inflammatory acne vulgaris.
- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
- Cutaneous lesions including warts, scars and striae.
- Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte and venous malformations.
- Removal unwanted hair. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

The **Nd:YAG Laser handpiece** with wavelength 1064 nm comes with 4 different applicator spot diameters: 2x4, 3.5, 5.5 and 9.5 mm. The three smaller spot sizes (2x4, 3.5, 5.5 mm) are intended for:

- Benign vascular lesions such as, but not limited to treatment of: port wine stains, hemangiomas, Warts, superficial and deep telangiectasias (venulectasias), reticular veins (0.1-4.0 mm dia.) of the leg, rosacea, venus lake, leg veins, spider veins, poikiloderma of civatte and angiomas.
- Benign cutaneous lesions, such as, but not limited to: warts, scars, striae and psoriasis.
- Benign pigmented lesions such as, but not limited to: lentigos (age spots), solar lentigos (sun spots), cafe-au-lait macules, seborrheic keratosis, nevi and nevus of Ota, chloasma, verrucae, skin tags and keratosis.
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to: periocular wrinkles and perioral wrinkles.

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- The handpiece with a spot size of 9.5 mm is also is intended for removal of unwanted hair. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen and treatment of pseudofolliculitis barbae (PFB).

Predicate Devices:

Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
Viora Reaction System	K090221	July 1, 2009
Alma Harmony XL	K113810	March 8, 2012
OmniMax (Multi-Application Dermatological Treatment device family)	K111303	Dec 21, 2011

Substantial Equivalence to Predicate Devices

The Viora ***V-total***™ includes the ST applicator that is the same applicator that was cleared with the **Viora Reaction (K090221)** and 3 other applicators: Both Nd:YAG and IPL applicators are equivalent to the **Alma Harmony XL (K113810)** and **the Omnimax (K111303).** All have the same clinical indication and use the same technology.

(Handpiece and applicator in this submission have the same meaning).

Performance Standards:

V-total™ complies with

- ***IEC 60601-1*** Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems.

- ***IEC 60601-1-2*** Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

- ***IEC 60601-2-2*** - Medical Electrical Equipment-Part 2: Particular requirements for the safety of high frequency surgical equipment.

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- **IEC 60601-2-22** - Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

- **IEC 60825-1** - Safety of laser products - Part 1: Equipment classification, and requirements.

- **IEC 60601-2-57** - Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetics

A detailed description appears in **Section 14**.

Performance Bench Tests

Bench testing demonstrated that the ***V-total***™ is as safe and effective as the cleared predicate devices.

Summary of Pre-Clinical and clinical study

The ***V-total***™ is a combination of the cleared ***Viora Reaction System*** (K090221 ST applicator), *an* ***IPL handpiece*** *and an* **Nd:YAG handpiece** using similar clinical and technological parameters. The safety and efficacy of the Intense Pulse Light (IPL) treatments and Nd:YAG handpiece treatments had been shown by the predicate devices using the same parameters. The clinical safety and efficacy of the ST handpiece has been shown by the Viora Reaction system.

The safety and efficacy of RF bipolar energy treatments as being used by these two applicators are well established in scientific research and literature.

Due to the comprehensive animal and clinical studies already performed by the ***Viora Reaction (ST Applicator)*** predicates and other devices, published in scientific literature, and since the power and frequency of the ***Viora V-total***™ are well within the previously cleared ***Viora Reaction System,*** Viora believes that animal and clinical studies are not required to determine the safety and efficacy of the ***V-total***™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

Viora Ltd.
% Yoram Levy
Qsite
31 Haavoda Street
Binyamina, 30500
ISRAEL

Re: K133837
Trade/Device Name: Viora V-Total
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, PBX
Dated: March 6, 2014
Received: March 10, 2014

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133837

Device Name
Viora V-Total

Indications for Use *(Describe)*
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- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to: periocular wrinkles and perioral wrinkles.
- The handpiece with a spot size of 9.5 mm is also intended for treatment of: Laser skin resurfacing procedures for the treatment of: acne scars and wrinkles. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- The handpiece with a spot size of 9.5 mm is also is intended for removal of unwanted hair. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen and treatment of pseudofolliculitis barbae (PFB).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
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For BSA

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